Express Mail No. EM180791250US
PTO/SB/08A (08-03)
Approved for use through 07/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 4

Complete if Known	
Application Number	10/562,089
Filing Date	December 23, 2005
First Named Inventor	Catherine Lofton-Day
Art Unit	2161
Examiner Name	Not yet assigned
Attorney Docket Number	47675-165

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[1] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		US- 5565552	10-15-1996	Magda et al.	
		US- 5567810	10-22-1996	Weis et al.	
		US- 5574142	11-12-1996	Meyer, Jr. et al.	
		US- 5585481	12-17-1996	Arnold, Jr. et al.	
		US- 5587371	12-24-1996	Sessler et al.	
		US- 5597696	01-28-1997	Linn et al.	
		US- 5786146	07-28-1998	Herman et al.	
		US- 5958773	09-28-1999	Monia et al.	
		US- 6251594	06-26-2001	Gonzalgo et al.	
		US- 6265171	07-24-2001	Herman et al.	
		US- 6331393	12-18-2001	Laird et al.	
		US- 10/603,138	06-23-2003	Lofton-Day et al.	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]-Number[4]-Kind Code[5] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T[6]
		WO 95/00669	01-05-1995	Pharmacia Biotech AB		
		WO 95/15373	06-08-1995	McGill University		
		WO 97/46705	12-11-1997	Johns Hopkins		
		WO 99/28498	06-10-1999	Epigenomics GmbH		
		WO 00/26401	05-11-2000	Johns Hopkins		
		WO 01/75172	10-11-2001	University of Southern Califomia		

Examiner Signature		Date Considered	

EXAMINER: Initial if reference considered, whether or not citation is in conformation with MPEP 609. Draw line through citation if not in conformation and not considered. Include copy of this form with next communication to applicant. [1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04 [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard St. 16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /SB/

Express Mail No.EM180791250US
PTO/SB/08A (08-03)
Approved for use through 07/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 2 of 4

Complete if Known	
Application Number	10/562,089
Filing Date	December 23, 2005
First Named Inventor	Catherine Lofton-Day
Art Unit	2161
Examiner Name	Not yet assigned
Attorney Docket Number	47675-165

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
		BACHMAN et al., "Methylation-associated Silencing of the Tissue Inhibitor of Metalloproteinase-3 Gene Suggests a Suppressor Role in Kidney, Brain, and Other Human Cancers," Cancer Research, February 15, 1999, Volume 59	
		DATABASE, "H. sapiens CpG island DNA genomic MseI fragment, clone 97b5, forward read cpg97b5.ftla," XP002312906, retrieved from EBI accession no. EM_HUM:HS97B5F, October 23, 1995 (1 page)	
		EADS et al., "CpG Island Hypermethylation in Human Colorectal Tumors Is Not Associated with DNA Methyltransferase Overexpression," Cancer Research, May 15, 1999, pp. 2302-2306, Volume 59	
		EADS et al., "Epigenetic Patterns in the Progression of Esophageal Adenocarcinoma," Cancer Research, April 15, 2001, pp. 3410-3418, Volume 61	
		EADS et al., "Fields of Aberrant CpG Island Hypermethylation in Barrett's Esophagus and Associated Adenocarcinoma," Cancer Research, September 15, 2000, pp. 5021-5026, Volume 60	
		FEIL et al., "Methylation analysis on individual chromosomes: improved protocol for bisulphite genomic sequencing," Nucleic Acids Research, 1994, pp. 695-696, Volume 22, Number 4	
		FROMMER et al., "A genomic sequencing protocol that yields a positive display of 5-methylcytosine residues in individual DNA strands," The Proceedings of the National Academy of Sciences, March 1992, pp. 1827-1831, Volume 89	
		GONZALGO et al., "Identification and Characterization of Differentially Methylated Regions of Genomic DNA by Methylation-sensitive Arbitrarily Primed PCR," Cancer Research, February 15, 1997, pp. 594-599, Volume 57	
		GONZALGO et al., "Rapid quantitation of methylation differences at specific sites using methylation-sensitive single nucleotide primer extension (Ms-SNuPE), Nucleic Acids Research, 1997, pp. 2529-2531, Volume 25, Number 12	
		GRIGG et al., "Sequencing 5-Methylcytosine Residues in Genomic DNA," BioEssays, June 1994, pp. 431-436, Volume 16, Number 6	
		GUT et al, "DNA and Matrix Assisted Laser Desorption Ionization Mass Spectrometry," Molecular Biology: Current Innovations and Future Trends, 1995, pp. 147-157, Horizon Scientific Press, Wymondham, United Kingdom	
		GUT et al., "A procedure for selection DNA alkylation and detection by mass spectrometry," Nucleic Acids Research, 1995, pp. 1367-1373, Volume 23, Number 8	
		HEID et al., "Real Time Quantitative PCR," Genome Research, 1996, pp. 986-994, Volume 6	
		HERMAN et al., "Inactivation of the CDKN2/p16/MTS1 Gene Is Frequently Associated with Aberrant DNA Methylation in All Common Human Cancer," Cancer Research, October 15, 1995, pp. 4525-4530, Volume 55	
		HERMAN et al., "Methylation-specific PCR: A novel PCR assay for methylation status of CpG islands," The Proceedings of the National Academy of Sciences, September 1996, pp. 9821-9826, Volume 93	
		HILTUNEN et al., "Hypermethylation of the APC (Adenomatous Polyposis Coli) Gene Promoter Region in Human Colorectal Carcinoma," The International Journal of Cancer, 1997, pp. 644-648, Volume 70	
		KARAS et al., "Laser Desorption Ionization of Proteins with Molecular Masses Exceeding 10 000 Daltons," Analytical Chemistry, October 15, 1988, pp. 2299-2301, Volume 60, Number 20	

Examiner Signature		Date Considered	

EXAMINER: Initial if reference considered, whether or not citation is in conformation with MPEP 609. Draw line through citation if not in conformation and not considered. Include copy of this form with next communication to applicant. [1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04 [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard St. 16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /SB/

Express Mail No. EM180791250US
PTO/SB/08A (08-03)
Approved for use through 07/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 3 of 4

Complete if Known	
Application Number	10/562,089
Filing Date	December 23, 2005
First Named Inventor	Catherine Lofton-Day
Art Unit	2161
Examiner Name	Not yet assigned
Attorney Docket Number	47675-165

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
		MARTIN et al., "Genomic sequencing indicates a correlation between DNA hypomethylation in the 5' region of the pS2 gene and its expression in human breast cancer cell lines," Gene, 1995, pp. 261-265, Volume 157	
		OLEK et al., "A modified and improved method for bisulphite based cytosine methylation analysis," Nucleic Acids Research, 1996, pp. 5064-5066, Volume 24, Number 24	
		OLEK et al., "The pre-implantation ontogeny of the H19 methylation imprint," Nature Genetics, November 1997, pp. 275-276, Volume 17	
		REIN et al., "Identifying 5-methylcytosine and related modifications in DNA genomes," Nucleic Acids Research, 1998, pp. 2255-2264, Volume 26, Number 10	
		SADRI et al., "Rapid analysis of DNA methylation using new restriction enzyme sites created by bisulfite modification," Nucleic Acids Research, 1996, pp. 5058-5059, Volume 24, Number 24	
		SANGER et al., "DNA Sequencing with chain-terminating inhibitors," The Proceedings of the National Academy of Sciences, December 1977, pp. 5463-5468, Volume 74, Number 12	
		TOYOTA et al., "CpG island methylator phenotype in colorectal cancer," The Proceedings of the National Academy of Sciences, July 1999, pp. 8681-8686, Volume 98	
		TOYOTA et al., "Identification of Differentially Methylated Sequences in Colorectal Cancer by Methylated CpG Island Amplification," Cancer Research, May 15, 1999, pp. 2307-2312, Volume 59	
		VAN DER KROL et al., "Modulation of Eukaryotic Gene Expression by Complementary RNA or DNA Sequences," BioTechniques, 1988, pp. 958-976, Volume 6, Number 10	
		VAN RIJNSOEVER et al., "Characterisation of colorectal cancers showing hypermethylation at multiple CpG islands," Gut, 2002, pp. 797-802, Volume 51	
		XIONG et al., "COBRA: a sensitive and quantitative DNA methylation assay," Nucleic Acids Research, 1997, pp. 2532-2534, Volume 25, Number 12	
		YAN et al., "CpG Island Arrays: An Application toward Deciphering Epigenetic Signatures of Breast Cancer," Clinical Cancer Research, April 2000, pp. 1432-1438, Volume 6	
		YOUNG et al., "HPP1: A transmembrane protein-encoding gene commonly methylated in colorectal polyps and cancers," The Proceedings of the National Academy of Sciences, January 2, 2001, pp. 265-270, Volume 98, Number 1	
		YU et al., "Specific Inhibition of PCR by Non-Extendable Oligonucleotides Using a 5' to 3' Exonuclease-Deficient DNA Polymerase," BioTechniques, 1997, pp. 714-720, Volume 23, Number 4	
		ZESCHNIGK et al., "Imprinted segments in the human genome: different DNA methylation patternsn in the Prader-Willi/ Angelman syndrome region as determined by the genomic sequencing method," Human Molecular Genetics, 1997, pp. 387-395, Volume 6, Number 3	
		ZESCHNIGK et al., "A single-tube PCR test for the diagnosis of Angelman and Prader-Willi syndrome based on allelic methylation differences at the SNRPN locus," European Journal of Human Genetics, March-April 1997, pp. 94-98, Volume 5, Number 2	

Examiner Signature		Date Considered	

EXAMINER: Initial if reference considered, whether or not citation is in conformation with MPEP 609. Draw line through citation if not in conformation and not considered. Include copy of this form with next communication to applicant. [1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04 [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard St. 16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /SB/

Express Mail No.EM180791250US
PTO/SB/08A (08-03)
Approved for use through 07/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 4 of 4

Complete if Known	
Application Number	10/562,089
Filing Date	December 23, 2005
First Named Inventor	Catherine Lofton-Day
Art Unit	2161
Examiner Name	Not yet assigned
Attorney Docket Number	47675-165

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
		ZON, "Oligonucleotide Analogues as Potential Chemotherapeutic Agents," Pharmaceutical Research, 1988, pp. 539-549, Voume 5, Number 9	

Examiner Signature	/Sarae Bausch/	Date Considered	06/20/2010

EXAMINER: Initial if reference considered, whether or not citation is in conformation with MPEP 609. Draw line through citation if not in conformation and not considered. Include copy of this form with next communication to applicant. [1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04 [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard St. 16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /SB/